Remarks

In accordance with the kind suggestions offered by the Examiner the errors on pages 19 and 20 have been corrected and the heading numbering adjusted. An error relating to non conformity of the heading and text for item 7, has been corrected. It is applicants position that this is not new matter.

Applicant respectfully declines to change the page of the claim pages, as this numbering was inserted by WIPO, however if the Examiner wishes to make this change she is authorized to do so. Since the undersigned is not certain whether reference has been made to the priority claim, insertion as shown on page 1 at line 10 is requested, if this reference is already present the request should be ignored.

The surplusage at claims 10 and 21 has been corrected.

New claims 42-49 have been added. These claims are specifically directed to devices of the present invention for the detection of hydrogen peroxide plasma.

Claim 1 has been restricted to plasma. This amendment, it is submitted takes the claim out of the scope of the disclosure of Ignacio, even though, as pointed out below, plasma is mentioned in that specification

Applicant respectfully traverses the rejection of claims 1-21,24,27-41 under 35 USC 102(e) over Ignacio .

Applicant has carefully studied the points made by the Examiner with respect to Ignacio and does not traverse the facts the examiner sets forth. However it is applicant's position that this exposition, while it addresses many similarities does not address the critical differences between the two inventions. Two of these relate to plasma and paper.

It should be pointed out that plasma is a state of matter which is quite different from that of vapor derived from the same substrate. Thus a device which is suitable for testing for liquid peracid or vapor thereof, does not suggest its utility in testing for plasma. Plasma is an extremely reactive state of matter, far more so than its liquid or vapor state. At column 5 line 55, Ignacio does indeed mention plasma in passing. There is no further reference to plasma in their text. This is not surprising as one skilled in the art who tried to apply the Ignacio teaching to plasma detection would fail if plasma was actually present. Not only that, but use of paper in a test device for plasma, will automatically turn the device off (see below). . The reason for this is that contrary to the device of applicant which uses a polymeric substrate, Ignacio uses paper as a substrate. It is well accepted in the art that plasma will burn up paper very rapidly.

In support of this position there is enclosed herewith a copy of Department of Defense publication entitled:" *Low temperature oxidative sterilization methods for sterilizing medical devices*". (Filed with previous response to the Official Action)

On the first page, second paragraph, the methodology for creation of hydrogen peroxide plasma is set forth. As will be seen, plasma is ionically charged. Thus plasma will NOT work in the Ignacio device not only because of the paper problem, but it would be discharged by the barrier film which is a critical part of this device. Such a barrie, of course, is absent from applicant's device.

On the second and third pages incompatibility with cellulosic materials such as paper is mentioned.

There are yet further differences which take the present invention out of any shadow of 35 USC 102 as well as 103 based on Ignacio.

The color change in the reference appears to be based on halogenation. This of course is a totally different chemical reaction from **hydro**halogenation which is the basis of the color change in the present invention. By no stretch of the imagination does one teach, or even suggest the other.

The device of the present invention permits **direct** contact with the material being tested, ie the plasma. Furthermore, unless the "wedge" modification is being used, in the present invention, the color change is uniform across the entire test strip. In the reference, the color change spreads from one edge to the center.

Presumably because of the nature of the materials being tested in the reference, a "vapor head space" and a barrier film are critical to its success. These are both absent in applicant's device.

Applicant's device is quite simple, while the reference device is substantially more complex.

Hence the alleged teaching of the present invention by Ignacio is in fact a false lead. Ignacio should therefore be withdrawn is a reference and the rejection falls.

In view of the clear inapplicability of Ignacio, there is no need to discuss the relevance or otherwise of Sato.

In view of the foregoing, it would appear that there is no tenable ground for rejection of any of the claims in the present application, and their prompt passage to issue is respectfully solicited.

This is to certify that the foregoing paper was transmitted by telefax to the Commissioner for Patents at 703 872 9306 on June 22nd 2004

Respectfully submitted,

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Version with markings showing changes made

In the claims:

Claims 1, 10, and 21 have been amended as follows:

New Claims 42-49 have been added as follows:

1.(Currently Amended) A device for monitoring ~~an oxidizing vapor or~~ plasma comprising:

at least one layer of polymer, having incorporated therein

a) an indicator capable of undergoing at least one color change

b) an activator for said indicator wherein said activator, when contacted with said ~~an oxidizing vapor or~~ plasma, undergoes a reaction wherein the product of said reaction causes said indicator to undergo said color change.

2.(Original) The device of claim 1 wherein the said indicator comprises at least one member of the group consisting of pigments, dyes, precursors of said dyes, and mixtures of any of the foregoing group members.

3. (Original) The device of claim 1 wherein the said indicator is a pH-sensitive sensitive dye.

4. (Original) The device of claim 1 wherein the said indicator is phenol red, m-cresol purple, pararosaniline or mixtures thereof.

5. (Original) The device of claim 1 where the said indicator undergoes halogenation or oxidation.

6. (Original) The device of claim 1 wherein the said indicator undergoes a yellow-to-blue, red-to-yellow or red-to-blue color change.

7. (Original)The device of claim 1 wherein said polymer is soluble in an organic solvent .

8. (Original)The device of claim 1 wherein said polymer is soluble in water or is water dispersible.

9. (Original) The device of claim 8 wherein said polymer is a water soluble or water dispersable homopolymer, or a copolymer or a mixture thereof.

10.(Currently Amended) The device of Claim 1 wherein said polymer is a polymer of ~~styrene,~~ acrylate, acrylic acid, acrylamide, vinyl acetate, vinyl alcohol, vinyl chloride, styrene, polyurethanes, cellulose nitrate, carboxymethyl cellulose or a mixture thereof.

11. (Original) The device of claim 10 wherein said polymer is a homopolymer, or a copolymer or a mixture thereof.

12. (Original) The device of claim 8 wherein said polymer is a polymer of styrene, acrylate, acrylic acid, acrylamide, vinyl acetate, vinyl alcohol, vinyl chloride, styrene, polyurethanes, cellulose nitrate, carboxymethyl cellulose or a mixture thereof.

13. (Original) The device of claim 1 wherein the polymer is an acrylate polymer.

14. (Original) The device of claim 1 wherein the polymer is cellulose nitrate or carboxymethylcellulose.

15. (Original) The device of claim 1 wherein the reaction product of said activator and said plasma is a halo-acid.

16. (Original) The device of claim 1 wherein the said activator is a salt.

17. (Original) The device of Claim 1 wherein said activator a halide.

18. (Original) The device of Claim 1 wherein said activator is a bromide.

19. (Original) The device of claim 1 wherein the said activator is a bromide of alkali metal or quaternary amine.

20. (Original) The device of claim 1 wherein said activator is tetrabutylammonium bromide or tetraethylammonium bromide or mixture thereof.

21.(Currently Amended) The device of claim 1 wherein said activator is a salt of an amine and an organic or inorganic acid ~~acid~~ .

22. (Original) The device of claim 1 wherein said activator is a thiocyanate.

23. (Original) The device of claim 1 wherein said activator is sodium thiocyanate.

24. (Original) The device of claim 1 additionally comprising an additive to control the diffusion of plasma gases.

25. (Original) The device of claim 1 additionally comprising a crosslinking agent or a plasticizer to control the diffusion of plasma gases.

26. (Original) The device of claim 1 additionally comprising a zinc compound or a polyaziridine to control the diffusion of plasma gases.

27. (Original) The device of claim 1 comprising two layers.

28. (Original) The device of claim 1 additionally comprising a polymeric top layer.

29. (Original)The device of claim 1 additionally comprising a wedge shaped polymeric top layer.

30. (Original) The process of making a device of claim 1 which comprises dissolving or dispersing the components thereof in a solvent therefor, applying the thus formed solution or dispersate to a substrate and permitting the solvent to evaporate.

31. (Original) The process of claim 30 wherein the substrate is a container for an item to be sterilized.

32. (Original) The process of claim 30 wherein the substrate is a plastic film, paper or metal.

33. (Original) The process of claim 30 wherein the substrate is polyester film or spun bonded polyolefins.

34. (Original) The process of claim 30 wherein the solution is an ink formulation.

35. (Original) The process of claim 30 wherein the solution is an aqueous ink formulation.

36. (Original) The process of claim 35 said ink formulation comprises an acrylate polymer.

37. (Original) A process of using a device of claim 1 for monitoring sterilization of materials comprising the steps of

a) affixing the device to said materials or containers containing same

b) carrying out the process of sterilization including the step of introducing the plasma into a vessel containing said materials or containers therefore and

c) observing the presence of a color change of said device.

38. (Original) The process of claim 37 wherein the plasma is derived from a member selected from the group consisting of hydrogen peroxide, perchloric acid and oxygen.

39. (Original) The process of claim 37 wherein the plasma is that derived from hydrogen peroxide.

40. (Original) A process of using the device of claim 1 for monitoring an oxidizing vapor comprising the steps of

a) exposing the device to an oxidizing vapor,

b) observing the presence of color change in the device.

41. (Original) The process of claim 40, wherein the oxidizing vapor is ozone or hydrogen peroxide.

42. (New) A device for monitoring hydrogen peroxide plasma comprising:
at least one layer of polymer, having incorporated therein
a) an indicator capable of undergoing at least one color change
an activator for said indicator wherein said activator, when contacted with said plasma, undergoes a reaction wherein the product of said reaction causes said indicator to undergo said color change.

43. (New) The device of claim 42 wherein said polymer is soluble in water or is water dispersible.

44. (New) The device of claim 43 wherein said polymer is a water soluble or water dispersable homopolymer, or a copolymer or a mixture thereof.

45. (New) The device of Claim 43 wherein said polymer is a polymer of acrylate, acrylic acid, acrylamide, vinyl acetate, vinyl alcohol, vinyl chloride, styrene, polyurethanes, cellulose nitrate, carboxymethyl cellulose or a mixture thereof.

46. (New) The device of claim 45 wherein the polymer is an acrylate polymer.

47. (New) The device of claim 45 wherein the polymer is cellulose nitrate or carboxymethylcellulose.

48. (New) A process of making a device of claim 42 which comprises dissolving or dispersing the components thereof in a solvent therefor, applying the thus formed solution or dispersate to a substrate and permitting the solvent to evaporate.

49. (New) A process of using a device of claim 42 for monitoring sterilization of materials comprising the steps of

a) affixing the device to said materials or containers containing same

b) carrying out the process of sterilization including the step of introducing hydrogen peroxide plasma into a vessel containing said materials or containers therefore and

c) observing the presence of a color change of said device.